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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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18M2/0808

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| ART UNIT | PAPER NUMBER |
| 1808 | |

DATE MAILED: 08/08/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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|------------------------------|---------------------------------------|---|
| Office Action Summary | Application No. 08/716,344 | Applicant(s) Rolf Engstad et al |
| | Examiner Francisco C. Prats | Group Art Unit 1808 |

Responsive to communication(s) filed on _____.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-16 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-16 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit:

DETAILED ACTION

1. Claims 1-16 are presented for examination.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. PCT/IB95/00265, filed on April 18, 1995.

Specification

3. The disclosure is objected to because of the following informalities:

The word -- particularly -- is misspelled as "particularly" throughout the specification and claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Art Unit:

The claims recite the use of a β -1,6-glucanase enzyme to prepare a β -glucan product. Claims 2 and 3 recite specific microorganisms that the enzyme is obtained from. However, the specification provides no guidance regarding how to obtain the enzyme. Moreover, the specification does not state how the enzyme is to be obtained from the microorganisms recited in claims 2 and 3. Because the specification lacks any guidelines for the preparation of the enzyme required to practice the claimed invention, the skilled artisan would expect to have to undertake a trial and error process to determine a procedure for isolating the claim-designated glucanase enzyme. The level of experimentation in such a trial and error process would clearly be considered to be undue. A holding of non-enablement is therefore proper.

5. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing, and therefore indefinite, because they are internally inconsistent and because it is not clear how the claimed product can result from treating *Saccharomyces*

Art Unit:

cerevisiae glucan with β -1,6-glucanase. Specifically, the claims recite a product having β -1,3 side chains attached by β -1,6 linkages. See e.g., claim 7. However, claim 1 recites that the β -1,6-glucanase must eliminate β -1,6-linked chains from the polysaccharide. Thus, the terminology used in the claims appears to be inconsistent because claim 1 requires the elimination of β -1,6-linked chains, whereas claim 7 simultaneously requires " β -1,3 side chains attached by β -1,6 linkages" yet also requires the glucan to be "essentially free of β -1,6-linked chains." Review of the specification, at page 4, lines 9-16, suggests that applicant intends to encompass the preparation of products wherein β -1,6-linked chains having more than one consecutively β -1,6-linked glucose residue are eliminated from a yeast glucan product. However, the current phraseology of the claims is internally inconsistent and therefore indefinite.

The recitation "essentially free" (claims 1, 7, 8, 9, 13 and 16) is indefinite because it is not clear what percentage of β -1,6-linked chains must be eliminated for a particular glucan to be considered essentially free of such chains.

Claim 2 is indefinite because the claim recites a single group, whereas the claim requires the microorganism to be selected from "groups."

Art Unit:

The recitation "suitable" is indefinite because no empirical criteria are set forth by which the skilled artisan can determine whether specific reagents and conditions are encompassed by the recitation "suitable." In sum, the word requires a subjective determination, and therefore is indefinite.

The phrases "characterized as" or "characterized by" (claims 7-9 and 16) are indefinite in that it is unclear whether the characteristic delineated is the only characteristic which defines a given product or material or whether the characteristic is only one of several other characteristics which are not delineated. Thus the phrase fails to clearly set the metes and bounds of the claimed invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced

Art Unit:

by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 9, 10 and 13 recite the broad recitation "especially from the yeast family Saccharomyces", and the claim also recites "particularly from the yeast species Saccharomyces cerevisiae" which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 4, 5, 7, 9, 10, 13, 14 and 16 rejected under 35 U.S.C. 102(b) as being anticipated by Shiota et al (J. Biochem. 98:1301-1307 (1985)).

Art Unit:

Shiota et al disclose a process wherein the claim-designated polysaccharide, *Saccharomyces cerevisiae* β -glucan, is hydrolyzed with the claim-designated enzyme. See p. 1303. ("Enzymatic hydrolysis of the skeletal glucan was performed with . . . *Neurospora crassa* endo-(β 1-6)-glucanase. The sample (about 100 mg) was incubated with . . . the endo-(β 1-6)-glucanase (2.8 U) in 2 ml of sodium acetate buffer (0.01 M, pH 5.0) at 35° C for 24 h."). Thus Shiota anticipates the claimed processes and products.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and

Art Unit:

potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiota et al (J. Biochem. 98:1301-1307 (1985)) in view of de la Cruz et al (Arch. Microbiol. 159:316-322 (1993)).

Claims 2 and 3 limit the β -1,6-glucanase of claim 1 to an enzyme obtained from *Trichoderma harzianum*. As discussed immediately above, Shiota anticipates claim 1. However, the β -1,6-glucanase used by Shiota is from a different microorganism than the claimed β -1,6-glucanase. Despite this difference, the artisan of ordinary skill at the time of applicant's invention would have recognized and reasonably expected that any β -1,6-glucanase, including the β -1,6-glucanase disclosed by de la Cruz, could have been used equivalently to the β -1,6-glucanase used in the Shiota process. Thus, because the process recited in claims 2 and 3 differs from Shiota only in the use of a known equivalent β -1,6-glucanase enzyme, the process recited in claims 2 and 3 would have been obvious at the time of applicant's invention.

10. Claims 1, 6 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiota et al (J. Biochem. 98:1301-1307 (1985)) in view of Jamas (U.S. Pat. 5,028,703).

Art Unit:

Claims 6 and 15 limit the processes of claims 1 and 13 to processes wherein specific extraction steps are performed. As discussed above, Shiota anticipates claims 1, 13 and 14. However, Shiota does not disclose processes wherein the exact process steps recited in claims 6 and 15 are performed. Despite this difference, Jamas discloses that, prior to acid or enzymatic treatment, glucan derived from *Saccharomyces cerevisiae* can be extracted from yeast using a variety of extraction techniques under a variety of conditions, including those employed in the process recited in claims 6 and 15. See e.g. Jamas at col. 6, lines 3-6. ("The digested glucan particles can be, if necessary, subjected to further washings and extraction to reduce the protein and contaminant level to the preferred amounts hereinbefore indicated.") Moreover, the claimed repetition of extraction steps is disclosed by Shiota, which discloses numerous repetitions of the extraction steps.

Thus, while the exact sequence of process steps recited in claims 6 and 15 are not disclosed by either Shiota or Jamas, both of the references disclose that the claimed steps were conventional in the art at the time of applicant's invention. Thus, the artisan of ordinary skill at the time of applicant's invention would have deemed the process recited in claims 6 and

Art Unit:

15 obvious over the cited references, the claimed process being an optimization of the processes disclosed by Shiota and Jamas, using conventional extraction steps disclosed by those references.

11. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiota et al (J. Biochem. 98:1301-1307 (1985)) in view of Jamas (U.S. Pat. 5,028,703), and in further view of Matsueda et al (GB 2 076 418).

Claim 11 limits the process of claim 10 to one in which formic acid is employed as the acid solubilizing agent. As discussed above, Shiota anticipates claim 10. However, Shiota does not disclose processes wherein formic acid is employed as the acid solubilizing agent. Rather, Shiota employs acetic acid as the solubilizing agent. Despite this difference, Jamas, which also discloses the use of acetic acid as a glucan solubilizing agent, also discloses that other acids may be employed as solubilizing agents. See Jamas at col. 6, line 67, through col. 7, line 3. ("Acetic acid is preferred, due to its mild acidity, ease of handling, low toxicity, low cost and availability, but other acids may be used. Generally these acids should be mild enough to limit hydrolysis of the β (1-3) linkages.") Further

Art Unit:

still, Matsueda discloses that formic acid can be used as a pre-enzymatic hydrolysis solubilizing agent for an anti-tumor glucan having a β -1,3 glucan backbone and β -1,6 branch structures.

Thus, the artisan of ordinary skill at the time of applicant's invention would have deemed obvious the substitution of the formic acid of Matsueda for the acetic acid used in the Shiota process. The artisan of ordinary skill would have recognized from the James disclosure that acids mild enough to preserve the β -1,3 glucan backbone could have been used equivalently to the acetic acid used in the Shiota process, and would further have recognized from the Matsueda disclosure that formic acid is such an acid. Thus, the artisan of ordinary skill at the time of applicant's invention would have considered the use of formic acid recited in claim 11 to have been the substitution of one art-recognized equivalent for another, and therefore obvious under § 103.

Claim Rejections - 35 USC § 102/103

12. Claims 8 and 12 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Shiota et al (J. Biochem. 98:1301-1307 (1985)).

Art Unit:

Shiota et al disclose a glucan product which appears to be identical to the presently claimed glucan product because the product results from contacting the claimed starting material, *Saccharomyces cerevisiae* glucan, with the claimed enzyme, β -1,6 glucanase. Consequently, the claimed product appears to be anticipated by the reference.

While it appears that the prior art product and the claimed product must necessarily be identical, it is noted that the prior art and claimed products are prepared by processes which differ somewhat in their initial extraction steps. However, even if the reference glucan and the claimed glucan are not one and the same and there is, in fact, no anticipation, the reference glucan would, nevertheless, have rendered the claimed glucan obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clearly close relationship between the products as evidenced by the fact that they are prepared from the same starting material, and are therefore structurally very closely related compounds.

Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Art Unit:

Regarding propriety of an alternative rejection, note that MPEP § 706.3(e) states that:

"[w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 35 U.S.C. 102 or 35 U.S.C. 103 of the statute is appropriate. As a practical matter, the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. A lesser burden of proof is required to make out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. *In re Brown*, 59 CCPA 1063, 173 USPQ 685 (1972) ; *In re Fessmann*, 180 USPQ 324 (CCPA1974) ."

In sum, these claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-1449 and/or PTO-892. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to F.C. Prats whose telephone number is (703) 308-3665.

Art Unit:

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Communications applicant wishes to submit by FAX should be submitted to FAX # (703) 305-4242 or (703) 305-3014.

F.C. Prats
August 4, 1997



FRANCISCO C. PRATS
PATENT EXAMINER
GROUP 1800